



Chester Labs

The Professional Advantage

377 01 AUG 31 10:16

August 29, 2001

Dockets Management Branch (HFA-305)
Docket No. 78N-036L
Food & Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sir or Madam:

I received your request for information relating to the safety of OTC sodium phosphates enema. Chester Labs discontinued the manufacture of sodium phosphates enema in January 2001, however we do continue to distribute private label product and track customer complaints.

All complaints for the past 10 years have been pulled and will be reviewed to determine if Chester received any reports of serious adverse drug experiences during the period from 1991-2001. This evaluation will be completed by the end of the month and a follow-up report will be forwarded the first week of September.

Sincerely,

Holly Sherwood
Quality Assurance Manager

78N-036L

LET 194

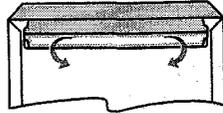
Plant & General Offices
1900 Section Road • Suite A • Cincinnati, Ohio 45237-3308
(513)458-3840 • (513)458-3858 Fax • (800)354-9709 • (800)235-3995 Fax
www.chester-labs.com



1 Peel off old labels



2 Fold this flap down



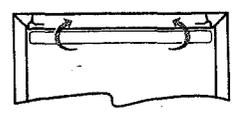
3 Expose adhesive



4 Fold top flap down



5 Press this flap up to seal



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